

Student Guide To Ethics Review For Research Involving Human Subjects

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Overview

The review of research involving human subjects at McGill is dictated principally by the Tri-Council Policy Statement (TCPS): *Ethical Conduct for Research Involving Humans*, as well as by other applicable federal and provincial regulations such as the Quebec Civil Code and the Food and Drug Act. All institutions who receive funding from the three major federal funding agencies are required to sign a Memorandum of Understanding with the agencies that requires, among other things, adherence to the principles and articles in the TCPS for all research (funded or non-funded) involving human subjects.

Who needs to get ethics review ?

- All research involving human subjects conducted at, or under the auspices of McGill University, must be reviewed and approved by the appropriate McGill approved Research Ethics Board (REB), before the research begins. The requirement for review applies to research conducted by or under the supervision of any member of McGill University, ***including student research projects conducted as part of thesis or course requirements.***
- Research conducted in other institutions, or in the field, whether in Canada or elsewhere, must be reviewed and approved by a McGill authorized REB before the research may begin.
- The requirement for review also applies to research or subject recruitment conducted by organizations or individuals who are not McGill members, while on University premises or using University facilities, equipment or resources.
- Students whose research involved human subjects must provide a copy of the approved ethics certificate for the research they conducted when they submit their thesis.
- Funded projects, whether granting agencies, contracts, internal funding or student research fellowships, will not have the funds released unless a valid ethics approval is provided

What is human subject research?

- The McGill *Policy On The Ethical Conduct of Research Involving Human Subjects* defines research as the systematic investigation to establish and communicate facts, principles, understandings or generalizable knowledge. The requirement for review covers a wide range of activities, encompassing the humanities, the social and behavioural sciences, as well as the biomedical sciences. Research involving human subjects runs the gamut from observing people in the mall to conducting a clinical oncology trial. It can include surveys and questionnaires, individual interviews or focus groups, physiological, psychological or educational testing, tissue collection, as well as therapeutic interventions.

- Research involving human subjects that requires review may include, but is not limited to, projects where data are derived from:
 - the collection of information through any interaction or intervention with a living individual
 - the secondary use of data previously collected from human subjects
 - the use of identifiable private information about an individual
 - human remains, cadavers, human organs, tissues and biological fluids, embryos or fetuses
 - interviewing an individual for information about another individual (third-party interviews)
 - naturalistic observation
- Research involving human subjects which *does not* require ethics review includes
 - research that only uses publicly available data (Statistics Canada data, published reports)
 - quality assurance studies, performance reviews or testing within normal educational requirements , unless an element of research is involved
 - observation of participants where it is evident they are seeking public visibility such as at political rallies, demonstrations or public meetings (other naturalistic observation does need ethics review)
 - interviews with people whose regular duties, such as public relations officers or public officials, involve communicating with the public on behalf of their organization on the selected interview topic
- Researchers are ultimately responsible for ensuring that the research they conduct has received the appropriate ethics review and they should always consult with the REB to clarify what types of research must be reviewed and what exceptions may exist.

What is a Research Ethics Board (REB)?

- This is the review body established within each institution to help ensure that ethical principles are applied to research involving human subjects. This involves the application of norms established by the Tri-Council Policy Statement (TCPS) *Ethical Conduct for Research involving Humans* and the relevant federal and provincial regulations.
- McGill has 6 REBs based on the range of research conducted at the University (4 social/behavioural/humanities and 2 biomedical REBs).
- Each of the McGill affiliated hospitals has their own REB. The REBs of the affiliated teaching hospitals are recognized as acting on behalf of the University for hospital-based research and are McGill authorized REBs. Investigators based in hospitals normally obtain ethics review through that hospital's REB. Multi-site projects conducted within several of the affiliated hospitals are normally reviewed by the Faculty of Medicine REB.

When and how do you get ethics review?

- You must obtain ethics approval from the appropriate REB before the research begins. Student research, such as for dissertations, theses, independent study projects and honour's theses, are reviewed in the same manner as faculty research, although student researchers must have a responsible faculty supervisor sign off on the ethics application.
- If a student's research project constitutes part of their supervisor's research program that has already received ethics approval, then further ethics approval is not needed provided the student's activities are covered in the existing approval. The student's name should then be added as a co-researcher on the proposal
- Students should refer to the REB's guidelines for information on what may constitute "course research" and can then be reviewed at the departmental level, rather than be submitted directly to the Research Ethics Board. Generally speaking, the intent of course projects is for the students to become more knowledgeable about research methods such as interviews, observation and survey techniques, rather than to contribute to generalizable knowledge, and the results of the data are not intended for publication or presentation outside the classroom. Department Review can only be used for projects where the subjects are competent adults, capable of giving free and informed consent and the topics and methods are considered to be of minimal risk.
- Refer to your designated REB for specific information on guidelines, submission deadlines, application forms, etc. A list of all McGill REBs can be found at www.mcgill.ca/researchoffice/compliance/human/
- A REB usually meets on a monthly basis and it may take between 2-8 weeks to receive final approval so check submission deadlines and plan accordingly.
- If your research involves hospital patients, staff, or data or will take place at a hospital, the project must be reviewed by that hospital. If it is a McGill affiliated hospital, or an institution of CRIR, then you do not need to also apply to the McGill REB. Always call and check to make sure you are getting the appropriate approvals.
- Approvals are only valid for a one-year period. Continuing review and approval is required annually for ongoing projects. The REB is to be notified when a project has terminated.
- Modifications to the project such as, but not limited to, changes in research design, subject recruitment or consent procedures, must be reviewed and approved by the REB before they can be initiated.
- Administrative changes to the research projects, such as the addition of funding sources, co-investigators, or title changes, must be documented by making an official modification request to the REB.

- If a project has been terminated, and ethics approval is no longer required, a Final Report form must be submitted to the REB.

NO RETROACTIVE APPROVALS ARE GIVEN

What happens if I don't get ethics approval?

- Noncompliance can include, but is not limited to failure to obtain REB approval before starting a research project, inadequate supervision of the research, failure to report adverse events or protocol changes to the REB, failure to provide ongoing progress reports, or significant deviation from the approved protocol without prior approval.
- Actions taken by an REB or the University administration, as appropriate, may include, but are not limited to, education measures, compliance audits, terminating or suspending REB approval of active studies, restrictions on the ability to serve as an investigator on research projects involving human subjects, freezing of research funds, or academic penalties in accord with the Code of Student Conduct and Disciplinary Procedures. Graduate students who do not have REB approval for projects involving human subjects risk non-acceptance of their thesis.

What are some of the responsibilities of graduate students and faculty supervisors?

- All researchers, including students, who conduct research with human subjects, must be familiar with the McGill Policy on the Ethical Conduct of Research Involving Human Subjects, the TCPS and with any other applicable ethical guidelines. Researchers must also be familiar with the policies and procedures of their respective Research Ethics Board. Researchers are ultimately responsible for ensuring that the research they conduct has received the appropriate ethics review and they should always consult with the REB to clarify what types of research must be reviewed and what exceptions may exist. Researchers have the primary responsibility to ensure that their research is carried out in an ethical manner. They are responsible for the protection of the rights and welfare of the human research subjects.
- All student research must be supervised by a faculty member who accepts responsibility for overseeing the ethical conduct of the student's research project. The supervising faculty member has certain responsibilities even though the student may be the primary researcher. Supervisors must ensure that their students have the training and competence needed to carry out their responsibilities in an ethical manner. They must ensure that the students are aware of and familiar with the contents of the McGill Policy on the Ethical Conduct of Research Involving Human Subjects and of other applicable ethical guidelines that are relevant to their responsibilities. Once a student's research project is

approved, the supervisor must take further reasonable measures to ensure that the research is conducted in accordance with the provisions of this policy and other applicable ethical requirements.

Where can you get more detailed information?

- All researchers, including students, must be familiar with the University Policy on the Ethical Conduct of Research Involving Human Subjects (www.mcgill.ca/researchoffice/compliance/human/) This document articulates the administrative structure, responsibilities and procedures for the ethical review of human subject research.
- Researchers must also be familiar with the policies and procedures of their respective Research Ethics Boards. Go to the website www.mcgill.ca/researchethics/compliance/human/ for a list of REBs and their guidelines and applications and for general information
- A suggested training tool is the TCPS online interactive tutorial (link is at www.mcgill.ca/researchoffice/compliance/human/) This is a valuable training tool which facilitates the use, interpretation and implementation of the Tri-Council Policy Statement: Ethical Conduct For Research Involving Human Subjects, the policy documents which McGill is required to adhere to. It includes case studies and a printable certificate of completion. Many institutions have already made this compulsory for all researchers who wish to conduct human subject research.
- You can contact Lynda McNeil (lynda.mcneil@mcgill.ca), Research Ethics Officer at 398-6831.